

EYE CLINIC

SERVING ALL OF BREVARD COUNTY

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The Dockets Management Branch (HFA - 305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

December 7, 1999

To Whom It May Concern:

It has just come to my attention that the FDA has proposed a rule to require screening and testing for risk **factors** for and clinical evidence of relevant **communicable** disease agents and diseases of donated corneas. As a practicing ophthalmologist and r&active surgeon in Brevard County, Florida for almost twenty years, I am disturbed by this news. It is evident that this proposal if passed threatens to reduce the **number** of surgical quality corneas **available** to physicians like myself. Unfortunately, the number of donations is low enough that there have been times in the past where the wait for a transplantable cornea has been months. I **fear** that through this proposal, my patients as well as other physicians patients will be unable to receive a necessary transplant at all.

The Florida Lions Eye Bank has been such a blessing to physicians like myself. In addition to providing over 1000 corneas to patients each year, they process, screen and provide corneas totally free of charge for transplant surgery. Which incidentally saves the US Government over one million dollars each year by cutting costs to Medicare **and Medicaid**. The **required** additional screening in my opinion will require an unnecessary and time **consuming** step in the process of obtaining corneas and would greatly hamper the accessibility of patients beii able to receive sight restoring transplant surgery. If the additional screening could ensure that the corneal tissue did not come from a donor having a communicable disease it would be agreeable that the additional testing was necessary, however requiring the time to **locate** next of kin (if able to at all) and get reliable information regarding the patient would not result in the additional **safety** of the corneas. I fear that this delay would only hinder the viability of the transplantable corneas **decreasing** tremendously the already short supply of corneas

This legislation profoundly needs to be **reassessed**, as it will have numerous negative **affects** on the public's well being. Should the Eye Banks have to begin charging for their services Medicare costs will increase tremendously and physicians will not be able to serve corneal blind patients as readily as we have in the **past**.

Please eliminate this requirement from the proposed **regulation**.

Sincerely,


Mukesh Aggarwal, MD
Medical Director/ President

cc: Senators Bob Graham and Connie **Mack**, Representatives Charles **Canady**, Dan Miller, Porter Goss, Dave **Weldon**, Mark Foley, Carrie Meek, **Illeana Ros-Lehtinen**, Robert Wexler, Peter Deutsch, Lincoln **Diaz-Barlart**, E. Clay Shaw Jr., Alcee **Hastings**

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